



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,431	12/14/2000	Richard S. Ginn	258/2999	1012

34313 7590 09/02/2003

ORRICK, HERRINGTON & SUTCLIFFE, LLP
4 PARK PLAZA
SUITE 1600
IRVINE, CA 92614-2558

EXAMINER

NERBUN, PETER P

ART UNIT	PAPER NUMBER
----------	--------------

3765

DATE MAILED: 09/02/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/738,431

Applicant(s)

GINN ET AL.

Examiner

Peter P Nerbun

Art Unit

3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,40,44-47,52,55,60-68,80 and 82 is/are pending in the application.
- 4a) Of the above claim(s) 45-47,52,64 and 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,40,44,53-55,60-62,65,67,68 and 82 is/are rejected.
- 7) ☒ Claim(s) 63 and 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 39, 40, 53-55, 60-62, 67, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Nelson et al, newly cited. The patent to Nelson et al discloses an apparatus comprising an elongate shaft 140, Fig. 16 having a proximal end and a distal end, an opening (adjacent ribs 152) in the proximal region of the elongate shaft, a plug member 154 disposed on the distal end of the elongate shaft, the elongate shaft having a cross-section that is substantially smaller than a cross-section of the plug member, and an opening (adjacent ribs 156) in the distal region of the plug, wherein said plug member and said elongate shaft have a lumen therein which extends from the opening in the distal region of said plug to the opening in the proximal region of said elongate shaft. With regard to the preamble of claims 39 and 60 where applicant recites the manner in which the apparatus is intended to be employed (viz. "for sealing a passage

Art Unit: 3765

through tissue") it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). It is noted, however, that the apparatus of Nelson et al may have a one way valve (see col. 17, lines 18-20) which seals against a particular direction of fluid flow through the tissue that separates the right atrium of the heart from the heart's left ventricle.

Claims 39, 40, 53, 54, 60-62, and 67 are further rejected under 35 U.S.C. 102(e) as being anticipated by Freeman et al, newly cited. The patent to Freeman et al discloses an apparatus comprising an elongate shaft 14, Figs. 1, 3 having a proximal end and a distal end, an opening 22 in the proximal region of the elongate shaft, a plug member 28 disposed on the distal end of the elongate shaft, the elongate shaft having a cross-section that is substantially smaller than a cross-section of the plug member, and an opening 24 in the distal region of the plug, wherein said plug member and said elongate shaft have a lumen 18, 24, Fig. 3 therein which extends from the opening in the distal region of said plug to the opening in the proximal region of said elongate shaft.

Claim 82 is rejected under 35 U.S.C. 102(b) as being anticipated by Frassica, taken as applied in the previous Office action. The patent to Frassica discloses an apparatus comprising an elongate member 502, Fig. 31A having a proximal end and a distal end, and a plug member 501, Fig. 31A substantially permanently attached to the distal end of the elongate shaft, the plug member comprising a helical thread 503, Fig. 31A on its outer surface, the elongate member having a cross section that is

substantially smaller than a cross section of the plug member, wherein said plug member and said elongate shaft have a lumen 508, Figs. 30, 31A therein which extends from the distal end of said plug to the proximal end of said elongate shaft. With regard to the preamble of claim 82 where applicant recites the manner in which the apparatus is intended to be employed (viz. "for sealing a passage through tissue") it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 63 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 44 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Barry et al, newly cited. To construct the apparatus of Nelson et al with an infection-resistant material secured to the entire plug member (which would include the distal end) as suggested by Barry et al (see col. 4, lines 20-28) would have been obvious since this would reduce the risk of infection prevalent in implanted medical devices.

Claims 45-47, 52, 64, and 80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

Applicant's arguments filed July 21, 2003 have been fully considered. Applicant states that the Frassica reference, as applied in the rejection of claim 82, has a closed distal end and does not have an opening in its distal region. In this regard the examiner notes that claim 82 does not recite an opening in the distal region of the shaft. Applicant further states that Frassica does not disclose an apparatus for sealing a passage through tissue. As explained earlier it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed (e.g. in sealing a passage through tissue) does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Applicant further states that the no lumen is disclosed that permits flow of fluid into one end of the device and out of the other end of the device. Claim 82 does not recite such a feature. Applicant continues by stating that Frassica does not meet the terms of claim 82, as amended since no structure is shown having an opening at one end and an opening at the other end of a lumen which connects said openings. Claim 82 has not been amended and does not recite such structure. Applicant states that claim 39 is generic to claims 45-47, 64, and 80. Thus applicant concludes that if claim 39 is allowed then claims 45-47, 64, and 80 should be examined. At present claim 39 has been rejected. However if applicant presents an allowable claim 39 then claims 45-47 and 64 would likewise be deemed allowable. Claim 80,

Art Unit: 3765

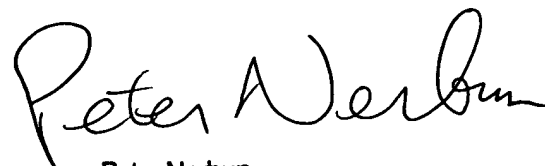
however, is an independent claim and is not directed to the elected species. Note that claim 80, lines 5-6 recites "a plug member releasably secured to the distal end of the elongate member by the connector". On page 15, lines 8-9 of the specification applicant describes the Figure 4 embodiment by stating that: "*Unlike the previous embodiment*, however, the plug member 220 is releasable from the shaft 212" (emphasis added). The "previous embodiment" that applicant refers to is the embodiment illustrated in Figure 3 which applicant elected in paper no. 13. Therefore the plug member 220 is disclosed as not being releasable from the shaft in the Figure 3 embodiment which means that claim 80 does not read upon the elected embodiment as disclosed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter P Nerbun whose telephone number is 703-308-0955. The examiner can normally be reached on M-F (1st Week) M-Th (2d Week).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John J Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0861.

Peter Nerbun
August 27, 2003


Peter Nerbun
Primary Examiner